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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,874	04/02/2004	Douglas Schein	115616	9059

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
06/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/815,874	SCHEIN ET AL.	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *27-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 47-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 March 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-8, 11-22, 26 and 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (US 6046046) in view of Dennehey (US 5462416).

With respect to claims 1-3, 7, 15 and 47, Hassanein discloses an apparatus for holding an organ comprising a portable housing (Figure 1:20) for enclosing the organ and a first set of tubes (Figure 2:54, 58, 64, 124). This is disclosed in column 8, lines 21-42 and throughout the reference. These tubes within the portable housing are connected to a separate set of corresponding delivery tubes using ports (Figure 5:292) arranged at the top of the portable housing. Hassanein, however, does not expressly state that the portable housing is reversibly connectable to a tube frame.

Dennehey discloses a removable tube frame assembly (see Figure 2:26) for holding a plurality of tubes at predetermined positions where they are directly connectable to various containers (Figure 2:20) and chambers (Figure 2:16). Smaller tube frame assemblies (Figure 3:22) are provided within the larger tube frame assembly (see also Figures 4-9) in order to further reroute a fluid moving through tubes within the larger tube frame assembly.

Hassanein and Dennehey are analogous art because they are from the same field of endeavor regarding blood and medical fluid transport and processing systems.

At the time of the invention, it would have been obvious to collect and arrange the tubes extending from the portable housing (20) of Hassanein using a tube frame similar to that disclosed by Dennehey. One of ordinary skill would have recognized that the tubes emerging from the top of the Hassanein portable housing are largely unorganized (see Figures 1 and 4-6), and therefore would have been motivated to consolidate and manage them using a tube frame in order to prevent tangling or damage. As evidenced by Dennehey, it is known in the art to provide a tube frame adjacent to a chamber or processing station to organize and position the fluid transporting tubes that directly connect to associated tubes within said chamber or processing station.

With respect to claims 4 and 5, Hassanein and Dennehey disclose the apparatus in claim 1. Hassanein further teaches in column 17, lines 3-20 that a soft pad (Figure 5:218) is provided for supporting an organ or tissue within an organ bath (Figure 5:212).

With respect to claim 6, Hassanein and Dennehey disclose the apparatus in claim 1. Hassanein additionally indicates that a filter (Figure 4:46) is in communication with tubing adapted to supply and withdraw fluid to and from the organ. This is described in column 8, lines 16-20.

With respect to claim 8, Hassanein and Dennehey disclose the apparatus in claim 1 wherein a pressure sensor capable of determining fluid pressure is connectable to the tube frame. Hassanein discloses the use of a control unit capable of detecting and regulating fluid pressure in column 18, line 12 to column 19, line 22.

With respect to claims 11 and 12, Hassanein and Dennehey disclose the apparatus in claim 1 wherein the plurality of tubes in the portable housing are connectible to an organ. This is depicted in at least in Figures 1, 2 and 5.

With respect to claims 13, 14, 17 and 22, Hassanein and Dennehey disclose the apparatus in claim 1. Furthermore, Hassanein teaches that the portable housing is reversibly attached to a plurality of external delivery tubes using various connectors (Figure 8:426) that regulate flow from the external tubes to the tubes within the portable housing. This connector is functionally equivalent to a clip, pin or snap in that it presses the portable housing tightly against an adjacent structure. Screws are considered to be well known means that would serve to hold a chamber or container in place.

With respect to claim 16, Hassanein and Dennehey disclose the apparatus in claim 1. Hassanein further teaches that the portable housing (Figure 1:20) is configured to be received by an organ diagnostic/transporter device (Figure 4:140) in the form of a analysis cart.

With respect to claims 18-21, Hassanein and Dennehey disclose the apparatus in claim 17 wherein a pump is provided for transporting fluids through the plurality of tubes found in the portable housing and the tube frame. This is described in column 7, lines 33-52 and throughout the reference. The use of conventional peristaltic type pumps (i.e. roller pumps) is additionally considered to be notoriously well known in the art.

With respect to claim 26, Hassanein and Dennehey disclose the apparatus in claim 1. Plastic is considered to be a well known material suitable for the construction of a tube frame. One of ordinary skill in the art would have been motivated to utilize plastic in the construction of the Hassanein tube frame due to its low cost and compatibility with known shaping techniques.

With respect to claims 48-53, Hassanein and Dennehey disclose the apparatus in claims 1 and 47. Additionally, Hassanein indicates in Figure 5 that the openings of the portable housing are configured to be horizontally aligned on a same horizontal plane. Furthermore, Dennehey teaches in Figure 12 that the tubes within the tube frame are horizontally aligned on the same horizontal plane. When the Dennehey tube frame is used in combination with the Hassanein portable housing, one of ordinary skill would have found it obvious and logical to align the tube frame and the openings of the portable housing adjacent to each other and on the same horizontal plane.

2) Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (US 6046046) in view of Dennehey (US 5462416) as applied to claim 1, and further in view of Toledo-Pereyra (US 4186565).

Hassanein and Dennehey disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a bubble trap is provided within the tube frame.

Toledo-Pereyra discloses an apparatus for holding an organ (Figure 2:K) comprising a portable housing (Figure 2:14) defining one or more openings and a tube frame (Figure 2:15) removably connectible to the portable housing. Column 1, line 51 to column 2, line 60 indicates that fluids located within the tube frame are transported to the portable housing using a system of tubes. The plurality of tubes in the tube frame are in communication with a plurality of tubes located within the portable housing in order to effectively introduce and withdrawn fluid to and from the organ. Furthermore, Toledo-Pereyra discloses that a bubble trap (Figure 2:17) is connectable to the tube frame and in communication with tubes located in the portable housing and the tube frame.

Hassanein and Toledo-Pereyra are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

At the time of the invention, it would have been obvious to provide the tube frame of Hassanein with a bubble trap capable of treating fluid upstream from the portable housing holding the organ/tissue. As evidenced by Toledo-Pereyra, bubble traps are common components of an organ perfusion system, and fulfill the function of removing

undesirable gases from a fluid stream before addition to the culture chamber. One of ordinary skill would have readily recognized the benefits of using a bubble trap when operating the Hassanein device, and would have been able to incorporate the bubble trap into the system of Hassanein in a predictable manner.

3) Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (US 6046046) in view of Dennehey (US 5462416) as applied to claim 17, and further in view of Fahy (US 5586438).

Hassanein and Cannon disclose the apparatus set forth in claim 17 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a sensor is provided for detecting proper and improper connection between the tube frame and the organ transporter.

Fahy discloses a lid position sensor capable of detecting when the lid of the organ holding chamber is ajar. Column 13, lines 16-35 state that when the lid is determined to be in an undesirable position, the sensors will convey this information to an operator through the use of an alarm or visual display.

Hassanein and Fahy are analogous art because they are from the same field of endeavor regarding organ/tissue perfusion systems.

At the time of the invention, it would have been obvious to include a detection system capable of determining when the tube frame of Hassanein is improperly connected to the organ transporter. This would have been beneficial because it would have prevent possible damage to the organ resulting from mechanical failures resulting

from improper connections. By ensuring that each component is properly connected to the other components, one would have been able to prevent tampering with the organ or excessive heat or contaminant infiltration.

Response to Arguments

Applicant's arguments filed 19 March 2010 with respect to the 35 U.S.C. 103 rejections regarding the combination of Bacchi and Cannon have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Hassanein and Dennehey.

The Hassanein reference expressly discloses a portable housing wherein the plurality of tubes (first tube set) within the portable housing are distinct from the delivery tubes located outside the portable housing. Hassanein teaches that the tubes within the housing communicate with the external tubes using ports (292) and/or connectors (428).

The Dennehey reference more clearly discloses a tube frame assembly wherein the tubes are horizontally oriented and in communication with associated process/analysis containers and chambers.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Kollar (US 20080027368) and Kamen (US 5628908) disclose the state of the art regarding tube frame assemblies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/
Examiner, Art Unit 1797